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Proposed Maximum Residue Limit

PMRL2014-20

Prothioconazole

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on various commodities to the product label of Proline 480 SC Foliar Fungicide, containing technical grade prothioconazole, is acceptable. The specific uses approved in Canada are detailed on the label of Proline 480 SC Foliar Fungicide, *Pest Control Products Act* Registration Number 28359.

The evaluation of this prothioconazole application indicated that the end-use product has merit and value and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a Maximum Residue Limit (MRL). A MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for prothioconazole is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Standards Council of Canada.

The proposed MRLs, to be added to the MRLs already established for prothioconazole, are as follows:

Table 1 Proposed Maximum Residue Limits for Prothioconazole

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Prothioconazole	2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione, including the metabolite α -(1-chlorocyclopropyl)- α -(2-chlorophenyl)methyl]-1H-1,2,4-triazole-1-ethanol	2.0	Crop subgroup 13-07B (Bushberry subgroup)
		0.3	Crop group 9 (Cucurbit vegetables)
		0.2	Crop subgroup 13-07H (Low growing berry subgroup, except strawberry)
		0.02	Peanuts

¹ ppm = parts per million

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data.

As per Table 2, the proposed MRLs in Canada are the same as the corresponding American tolerances as listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide, but differ from the Codex MRLs.¹ A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food website, by pesticide or commodity.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food commodity	Canadian MRL (ppm)	American tolerance (ppm)	Codex MRL (ppm)
Crop subgroup 13-07B (Bushberry Subgroup)	2.0	2.0	No MRL established
Crop Group 9 (Cucurbit vegetables)	0.3	0.3	No MRL established
Crop Subgroup 13-07H (Low growing berry subgroup, except strawberry)	0.2	0.2	No MRL established

¹ The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for prothioconazole up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

Appendix I

Summary of Field Trial Data Used to Support the Proposed Maximum Residue Limits

Residue data from field trials conducted in Canada and the United States of America were submitted to support the domestic use of Proline 480 SC Foliar Fungicide on cucumber, muskmelon, summer squash, blueberry, cranberry and peanuts. In addition, a processing study in treated peanuts was reviewed to determine the potential for concentration of residues of prothioconazole into processed commodities.

Maximum Residue Limits

The recommendation for MRLs for prothioconazole was based on the submitted field trial data, and the guidance provided in the Organisation for Economic Co-operation and Development's MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs for Crop Group 9 (Cucurbit vegetables), Crop Subgroup 13-07B (Bushberry subgroup), Crop Subgroup 13-07H (Low growing berry subgroup, except strawberry) and peanuts.

Table A1 Summary of Field Trial and Processing Data Used to Support Maximum Residue Limits

Commodity	Application method/ Total application rate (g a.i./ha)	Pre Harvest Interval (days)	Residues ¹ (ppm)		Experimental processing factor
			Min	Max	
Cucumber	Drip/drench and/or foliar spray/ 600	7	<0.040	<0.125	Not applicable
Muskmelon			<0.045	0.188	
Summer squash			<0.040	<0.079	
Blueberry	Foliar spray/400	7	<0.092	1.07	
Cranberry	Foliar spray/350	45	<0.040	<0.112	
Peanuts	Foliar spray/800	13-15	<0.02	<0.02	No concentration observed in refined oil, dry roasted peanuts or peanut butter

¹ Residues of prothioconazole and desethio-prothioconazole in parent equivalents.

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of prothioconazole. Residues of prothioconazole in these crop commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.